IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF WISCONSIN

UNITED STATES OF AMERICA, Plaintiff, v. NATURAL OVENS BAKERY, INC., a corporation, and PAUL A. STITT, BARBARA R. STITT, and MATTHEW E. TAYLOR, individuals, Defendants.	)	Civil No. 06-C-147 CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, having filed a Complaint for Permanent Injunction against Natural Ovens Bakery, Inc. ("Natural Ovens"), a corporation, and Paul A. Stitt, Barbara R. Stitt, and Matthew E. Taylor, individuals (hereafter, collectively, "Defendants"), and Defendants having appeared and having consented to the entry of this Consent Decree of Permanent Injunction ("Decree") without contest and before any testimony has been taken, and the United States of America having consented to this Decree;

IT IS HEREBY ORDERED, ADJUDGED AND DECREED that:

I. This Court has jurisdiction over the subject matter and over all parties to this action.

II. The Complaint for Injunction states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq. ("the Act").

III. The United States alleges that Defendants violate:

A. 21 U.S.C. § 331(a) by introducing or causing to be introduced into

interstate commerce, or delivering or causing to be delivered for introduction into interstate commerce, foods that are misbranded within the meaning of 21 U.S.C. § 343(a)(1), and a drug that is misbranded within the meaning of 21 U.S.C. § 352(f)(1); and

B. 21 U.S.C. § 331(k) by causing foods that are held for sale after shipment in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 343(a)(1), and by causing a drug that is held for sale after shipment in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1); and

C. 21 U.S.C. § 331(d) by introducing or causing to be introduced into interstate commerce, or delivering or causing to be delivered for introduction into interstate commerce, an unapproved new drug.

IV. Upon entry of this Decree, Defendants and each and all of their agents, representatives, employees, attorneys, successors, assigns and any and all persons in active concert or participation with any of them, are permanently restrained and enjoined from directly or indirectly doing or causing to be done any of the following acts:

A. Introducing or delivering for introduction into interstate commerce any article of food, within the meaning of 21 U.S.C. § 321(f), including any dietary supplement, that is misbranded within the meaning of 21 U.S.C. § 343(a)(1), or any article of drug, within the meaning of 21 U.S.C. § 321(g), that is misbranded within the meaning of 21 U.S.C. § 352(f)(1);

B. Causing any article of food, within the meaning of 21 U.S.C. § 321(f),

including any dietary supplement, that is held for sale after shipment in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 343(a)(1) or causing any article of drug, within the meaning of 21 U.S.C. § 321(g), that is held for sale after shipment in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1);

C. Introducing or causing to be introduced into interstate commerce, delivering or causing to be delivered for introduction into interstate commerce, or manufacturing, processing, preparing, packing, holding, or distributing, at or from the Natural Ovens facility located at 4300 Highway CR, Manitowoc, Wisconsin (the Manitowoc facility), or at or from any other location, articles of drug; and

D. Failing to implement and continuously maintain the requirements of this Decree.

V. Within ten (10) calendar days of the entry of this Decree, Defendants shall select a person (or persons) ("expert(s)"), who is without any personal or financial ties (other than the consulting agreement) to Defendants or their families and who, by reason of background, experience, and education, is qualified to make inspections of Defendants' manufacturing facilities to determine whether the methods, facilities, and controls (including quality, production, and process controls) are adequate to ensure that each article of food manufactured, processed, prepared, packed, or held for sale by Defendants contains the quantity of each nutrient declared in the product's labeling, including but not limited to the Nutrition Facts panel, within the allowances provided for in FDA regulations and to determine whether the labeling of Defendants' food products, including dietary supplements, is in compliance with the Act and FDA regulations.

Defendants shall inform FDA in writing of the name(s) and qualifications of the expert(s) before retaining the expert(s).

VI. Within twenty (20) calendar days of the entry of this Decree, the expert(s) shall inspect Defendants' manufacturing facilities, including the Manitowoc facility, and manner of operating to determine whether the methods, facilities, and controls (including quality, production, and process controls) are adequate to ensure that each article of food manufactured, processed, prepared, packed, or held for sale by Defendants contains the quantity of each nutrient declared in the product's labeling, including but not limited to the Nutrition Facts panel, within the allowances provided for in FDA regulations.

VII. Within thirty (30) calendar days of the entry of this Decree, the expert(s) shall certify in writing to FDA that Defendants' manufacturing operations are adequate to ensure that each article of food manufactured, processed, prepared, packed, or held for sale by Defendants contains the quantity of each nutrient declared in the product's labeling, including but not limited to the Nutrition Facts panel, within the allowances provided for in FDA regulations and that Defendants have instituted written quality, production, and process controls, including:

1. procedures for the receipt, testing and handling of raw materials;
2. procedures for product formulation;
3. procedures for the monitoring of in-process production;
4. procedures for the labeling of finished products;
5. procedures for laboratory testing of finished products; and
6. procedures for the disposition of rejected components and rejected finished product.

If the expert(s) is unable to make this certification within thirty (30) calendar days of the entry of this Decree, Defendants shall, within forty (40) calendar days of the entry

of this Decree, submit a report to FDA detailing the deficiencies noted by the expert(s) and identify the corrective measures Defendants have taken, and plan to take, to ensure that Defendants' manufacturing operations are adequate to ensure that each article of food manufactured, processed, prepared, packed, or held for sale by Defendants contains the quantity of each nutrient declared in the product's labeling, including but not limited to the Nutrition Facts panel, within the allowances provided for in FDA regulations and that Defendants have instituted written quality, production, and process controls. Such a report shall include any production records, developmental data, or test records requested by FDA. With respect to each corrective action that Defendants cannot complete within sixty (60) calendar days of the entry of this Decree, Defendants shall submit to FDA a time frame for completion. Upon receipt of the report described in this paragraph, FDA may order reinspection and certification by the expert(s).

VIII. Within twenty (20) calendar days of the entry of this Decree, the expert(s) shall examine the labeling for all of Defendants' foods and certify in writing to FDA that Defendants have omitted any claims that cause the products to be drugs within the meaning of the Act and that the labeling, including but not limited to all nutrient and implied nutrient content claims, is in compliance with the Act and FDA regulations. If the expert(s) is unable to make this certification within twenty (20) calendar days of the entry of this Decree, Defendants shall, within thirty (30) calendar days of the entry of this Decree, submit a report to FDA detailing the deficiencies noted by the expert(s) and identify the corrective measures Defendants have taken, and plan to take, to ensure that Defendants have omitted any claims that cause the products to be drugs within the

meaning of the Act and that the labeling, including but not limited to all nutrient and implied nutrient content claims, is in compliance with the Act and FDA regulations. Such a report shall include any labeling requested by FDA. With respect to each corrective action that Defendants cannot complete within forty-five (45) calendar days of the entry of this Decree, Defendants shall submit to FDA a time frame for completion. Upon receipt of the report described in this paragraph, FDA may order reinspection and certification by the expert(s).

IX. Within twenty (20) calendar days of the entry of this Decree, Defendants, shall, under the expert's supervision and in accordance with methods approved by FDA, examine all articles of food and drug in the possession of or under the custody or control of Defendants at the time of entry of this Decree to ensure that such articles of food and drug are not misbranded under the Act and FDA regulations. Within thirty (30) calendar days of the entry of this Decree, Defendants shall submit written reports of such examination to FDA. Defendants, the expert(s), or FDA shall make such analyses as FDA deems necessary. The costs of all such analyses shall be borne by Defendants.

X. Within thirty (30) calendar days of the entry of this Decree, Defendants shall, under FDA supervision, according to procedures approved by FDA, and as and when directed by FDA, destroy or bring into compliance with the Act and FDA regulations to the satisfaction of FDA all finished foods in the Manitowoc facility or being elsewhere held for distribution by Defendants at the time of entry of this Decree.

XI. Within ten (10) calendar days of the entry of this Decree, Defendants shall identify a competent, independent laboratory (the laboratory) acceptable to FDA for the

testing of Defendants' foods to ensure that each article of food manufactured, processed, prepared, packed, or held for sale by Defendants contains the quantity of each nutrient declared in the product's labeling, including but not limited to the Nutrition Facts panel, within the allowances provided for in FDA regulations. Defendants shall obtain FDA approval, in writing, for the sampling methods and laboratory test methods to be used for the testing of Defendants' foods.

XII. Within twenty (20) calendar days of the entry of this Decree, Defendants shall collect samples of every finished food from each of their product lines (bread, bagels, cookies, rolls, muffins, granola bars, cereals and pancake mixes, supplement mixes, and chocolate) and have the samples tested by the laboratory in accordance with paragraph XI to ensure that the samples contain the quantity of each nutrient declared in the product's labeling, including but not limited to the Nutrition Facts panel, within the allowances provided for in FDA regulations. Defendants shall certify in writing to FDA that the products sampled and tested are marketed formulations. The provisions of this paragraph may be satisfied by the testing of product samples collected on or after January 16, 2006, if the sampling methods and laboratory test methods are satisfactory to FDA pursuant to paragraph XI.

XIII. Within two months of the entry of this Decree, Defendants shall sample half of their finished food products again and have the samples tested by the laboratory in accordance with paragraph XI to ensure that the samples contain the quantity of each nutrient declared in the product's labeling, including but not limited to the Nutrition Facts panel, within the allowances provided for in FDA regulations. Within four months of completion of the initial testing discussed in paragraph XII, Defendants shall sample the

other half of their finished food products and have the samples tested by the laboratory in accordance with paragraph XI to ensure that the samples contain the quantity of each nutrient declared in the product's labeling, including but not limited to the Nutrition Facts panel, within the allowances provided for in FDA regulations. Such sampling and testing in alternating halves of Defendants' finished food products shall be repeated every two months. Every one of Defendants' finished food products shall be tested a minimum of three times per year. The laboratory testing shall exclude tests for cholesterol. Defendants shall certify in writing to FDA that the products sampled and tested are marketed formulations. If this testing establishes for twelve consecutive months that Defendants' foods contain the quantity of each nutrient declared in their labeling, including but not limited to the Nutrition Facts panel, within the allowances provided for in FDA regulations, then Defendants shall sample every finished food product and have the samples tested by the laboratory in accordance with paragraph XI at least once every year thereafter.

XIV. Defendants shall maintain written records of the finished foods sampled and analyzed. Such records shall include, but not be limited to, the date and time of sampling, the lot numbers sampled, the types of products sampled, and the names of the persons doing the sampling. Defendants shall send FDA copies of such records each time samples are sent to the independent laboratory for testing. Defendants shall send to FDA written reports of all laboratory test results within one business day after receipt by Defendants. If any samples do not contain the quantity of each nutrient declared on the product's labeling, or are not within the variances allowed by FDA regulations, FDA may require any or all of the following:

A. that the lot from which the sample was collected be recalled by Defendants at their own cost and under FDA supervision;

B. that, within a time period determined by FDA, Defendants implement corrective measures to their manufacturing processes and labeling, as necessary, to prevent the manufacture of misbranded food. Defendants shall document such corrective measures in writing, and the written documentation shall be sent to FDA within one day after implementation;

C. that Defendants cease manufacturing that product until FDA approves Defendants' corrective measures in writing;

D. that Defendants take samples of each finished food from the entire product line from which the violative sample came and have the samples tested by the laboratory in accordance with paragraph XI. The conditions of paragraph XIII shall apply to this additional testing; and/or

E. that Defendants pay liquidated damages pursuant to paragraph XXVIII of this Decree.

XV. The expert(s) described in paragraph V shall, no less frequently than once every six months for a minimum of three years from the entry of this Decree, examine the labeling of all of Defendants' foods, including dietary supplements, to ensure that the labeling of these products is in compliance with the Act and FDA regulations. Within sixty (60) calendar days of commencing such examination, the expert(s) shall certify in writing to FDA and Defendants that the labeling of Defendants' foods is in compliance with the Act and FDA regulations. If the expert(s) is unable to make such a certification within sixty (60) calendar days of commencing of such examinations,

Defendants shall, within seventy-five (75) calendar days of the commencing of such examinations, submit a report to FDA detailing the deficiencies noted by the expert(s) and identify the corrective measures Defendants have taken, and plan to take, to ensure that the labeling of Defendants' foods is in compliance with the Act and FDA regulations. Such a report shall include any records or labeling requested by FDA relating to Defendants' compliance. With respect to each corrective action that Defendants cannot complete within seventy-five (75) calendar days of the commencing of such examinations, Defendants shall submit in writing to FDA a time frame for completion.

XVI. Within fifteen (15) calendar days after the entry of this Decree, Defendants shall provide a copy of it, by personal service or by certified mail, return receipt requested, to each and all of Defendants' agents, representatives, employees, attorneys, successors, assigns, and any persons in active concert or participation with any of them. Defendants shall also, within fifteen (15) calendar days after the entry of this Decree, post a copy of this Decree in the employee common areas at the Manitowoc facility and any other facility at which Defendants manufacture, process, prepare, pack or hold food and/or drugs.

XVII. Within twenty (20) calendar days after the entry of this Decree, Defendants shall provide to FDA and Plaintiff's attorneys, an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of Defendants' compliance with paragraph XVI, and identifying the names and positions of all persons who were notified pursuant to paragraph XVI.

XVIII. Upon entry of the Decree, Defendants shall, within fifteen (15) calendar

days of employment of any new employee, provide a copy of the Decree, by personal service or by certified mail, return receipt requested, to all new employees hired by Defendants.

XIX. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of the Manitowoc facility, or of any other facility at which Defendants manufacture, process, prepare, pack or hold food and/or drugs, and, without prior notice and as and when FDA deems necessary, to take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree. Such inspections may, at FDA's discretion, include the taking of photographs and samples and the examination and copying of all records that relate to the manufacture, processing, preparing, packing, holding, or distribution of food and/or drugs. Such inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is apart from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

XX. Defendants shall promptly provide any information or records to FDA upon request regarding the manufacture, processing, preparing, packing, holding, or distribution of food and/or drugs. Defendants shall maintain copies of all such records at the Manitowoc facility in a location where they are readily available for reference and inspection by FDA representatives. All records shall be presented immediately to FDA investigators upon request.

XXI. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, analysis of a sample or samples, or other information, that

Defendants have failed to comply with any provision of this Decree, have violated the Act or FDA regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, or FDA regulations, FDA may, as and when it deems necessary, require Defendants to take appropriate action, including, but not limited to, requiring Defendants immediately to take one or more of the following actions:

A. Cease manufacturing, processing, preparing, packing, holding, and distributing any or all articles of food and drug;

B. Recall any affected articles of food or drug that have been distributed or are under the custody and control of Defendants' agents, distributors, customers, or consumers;

C. Institute or re-implement any of the requirements set forth in this Decree;

D. Defendants pay liquidated damages pursuant to paragraph XXVIII of this Decree; and/or

E. Take any other corrective actions as FDA, in its discretion, deems necessary to bring Defendants into compliance with this Decree, the Act, or FDA regulations. All costs of such recall(s) and corrective actions shall be borne by Defendants. The costs of FDA inspections, sampling, testing, travel time, and subsistence expenses to implement the remedies set forth in this paragraph shall be borne by Defendants at the rates specified in paragraph XXIII. This provision shall be separate and apart from, and in addition to, all other remedies available to FDA.

XXII. Any cessation of operations or other corrective actions as described in

paragraph XXI shall continue until Defendants receive written notification from FDA that Defendants

appear to be in compliance with the Act, FDA regulations, and this Decree, which notification shall not be unreasonably withheld.

XXIII. Defendants shall pay the costs of FDA's supervision, inspection, analysis, review, and examination conducted pursuant to this Decree at the standard rates prevailing at the time the activities are accomplished. FDA shall provide to Defendants a reasonably detailed bill of costs. As of the date of entry of this Decree, these standard rates are: $69.37 per hour and fraction thereof per representative for inspection and supervision work other than laboratory and analytical work; $83.15 per hour and fraction thereof per person for laboratory and analytical work; $0.445 per mile for travel by automobile; the government rate or equivalent for travel by air; and the published government per diem rate, or the equivalent, for the areas in which the inspections are performed, per representative for subsistence expenses, where necessary. In the event that the standard rates generally applicable to the FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of this Court.

XXIV. If any Defendant violates this Decree and is found in civil or criminal contempt thereof, that Defendant shall, in addition to other remedies, reimburse Plaintiff for its attorney fees (including overhead), investigational expenses, expert witness fees, and court costs relating to such contempt proceedings.

XXV. Defendants shall notify FDA, at least thirty (30) calendar days before any change in ownership, name, or character of this business that occurs after the entry of

this Decree, such as reorganization, relocation, assignment, or sale of the business that may affect compliance obligations arising out of this Decree. Defendants shall serve a copy of this Decree on any prospective successor or assignee at least thirty (30) calendar days prior to such sale or change of business, and shall furnish to FDA and to the Plaintiff's attorneys, an affidavit of compliance with this paragraph within fifteen (15) calendar days of such sale or change of business.

XXVI. All notifications, correspondence, and communications to FDA required by the terms of this Decree shall be submitted to the Director, FDA Minneapolis District, 212 Third Avenue South, Minneapolis, MN 55401. In the event that this address changes, FDA shall inform Defendants of the change, and all notifications, correspondence, and communications to FDA required by the terms of this Decree shall be sent by Defendants to the new address without further order of this Court.

XXVII. All decisions specified in this Decree shall be vested in the discretion of FDA and shall be final. FDA's decisions under this Decree shall be reviewed, if necessary, under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A) and shall be based exclusively upon the written record that was before FDA at the time of the decision. No discovery may be had by either party.

XXVIII. If Defendants fail to comply with any of the provisions of this Decree, then, on motion of the United States in this proceeding, Defendants shall pay to the United States of America the sum of one thousand dollars ($1,000) in liquidated damages per day, per product, for each violation. For purposes of this paragraph, each labeling violation shall be counted as a separate violation.

XXIX. This Court retains jurisdiction of this action and the parties hereto for the

purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary and appropriate.

XXX. No sooner than five (5) years after entry of this Decree, Defendants may petition this Court for an order dissolving the Decree. If Defendants have maintained to FDA's satisfaction a state of continuous compliance with this Decree, the Act, and all applicable regulations during the five (5) years preceding Defendants' petition, the government will not oppose such petition.

SO ORDERED:

Dated this 3rd day of February, 2006.

s/ William C. Griesbach
UNITED STATES DISTRICT JUDGE

We hereby consent to the entry of the foregoing Decree:

FOR DEFENDANTS

/s/ Paul A. Stitt
PAUL A. STITT
Individually and as Chairman and Owner of Natural Ovens Bakery, Inc.

/s/ Barbara R. Stitt
BARBARA R. STITT
Individually and as President of Natural Ovens Bakery, Inc.

/s/ Matthew E. Taylor
MATTHEW E. TAYLOR
Individually and as Chief Executive Officer of Natural Ovens Bakery, Inc.

/s/ Arthur Y. Tsien

Attorney for Natural Ovens Bakery, Inc.

/s/ Arthur Y. Tsien

Attorney for Paul A. Stitt

/s/ Arthur Y. Tsien

Attorney for Barbara R. Stitt

/s/ Arthur Y. Tsien

Attorney for Matthew E. Taylor

FOR PLAINTIFF

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United States Department of
Health and Human Services
Office of the General Counsel